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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,956	10/11/2001	Ronald W. Mink	044170-5052-01	7403

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EXAMINER

SORKIN, DAVID L

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 09/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/973,956

Applicant(s)

MINK ET AL.

Examiner

David L. Sorkin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 50-57 is/are pending in the application.
- 4a) Of the above claim(s) 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 50-57 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 50-56, drawn to an assay device, classified in class 422, subclass 61.
  - II. Claim 57, drawn to a method collection and assay of oral fluid, classified in class 436, subclass 174.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case oral fluids could be delivered to the device without placing the device in an oral cavity. For example, by spitting or using a transfer device such as a pipette or swab. Also, the assay device could be used with fluids which are not oral fluids, such as urine.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

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5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with James L. Reed on 22 August 2002 a provisional election was made without traverse to prosecute the invention of Group I, claims 50-56. Affirmation of this election must be made by applicant in replying to this Office action. Claim 57 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Priority***

8. The instant application is not entitled to any benefit of provisional application 60/079,952 because the provisional application is that of a different inventive entity and also because no corresponding non-provisional application was filed within 1 year of the filing of 60/079,952.

***Oath/Declaration***

9. Applicant is requested to review the accuracy of the declaration particularly regarding the claim to priority of provisional application 60/079,952, which appears to be that of an entirely different inventive entity, as well as the "I have reviewed and

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understand the contents of the above identified specification" statement, from the perspective that 60/079,952 is part of the specification as incorporated by reference.

***Specification***

10. The disclosure is objected to. In the amendment filed 11 October 2001, a statement concerning the parent application(s) was inserted. However, the original statement, in lines 6-8 of page 1, was not deleted. The (both) statements claiming the benefit of provisional application No. 60/079,952 are objected to, because the provisional application expired prior to the filing of a corresponding non-provisional application. Also, in line 7 of page 1, it is incorrectly stated that filing date of 60/079,952 is March 3<sup>rd</sup>.

***Claim Rejections - 35 USC § 112***

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 51-53, 55 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claims 51-53 are rejected because they depend from claim 1, which is canceled. For the purposed of examination with regard to the prior art, it will be assumed that claims 51-53 depend from claim 50.

14. Claims 55 and 56 are rejected because they depend from claim 5, which is canceled. For the purposed of examination with regard to the prior art, it will be assumed that claims 55 and 56 depend from claim 54.

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15. In claim 55, there is lack of antecedent basis for "the wick member second part", even assuming claim 55 depends from claim 54.

16. In claim 56, assuming it depends from claim 54, it is unclear what it meant by "the neck portion tapers from the narrow end width to the opening width". How can the neck portion be the same width as a channel it defines? Does "tapers" mean "gets smaller" as defined in dictionaries or does it mean "gets larger", in the context of the claim?

***Claim Rejections - 35 USC § 102***

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 50-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Seymour (US 5,380,492). Regarding claim 50, Seymour ('492) discloses a device comprising a housing (415,416,420) having a fluid receiving end (415) and an assay portion (416); a lateral flow assay strip (portion of 421 at and beyond 422, in a direction away from 415) contained within the assay portion; and a collection strip for transporting fluid from a fluid source to the assay strip, the collection strip including a first narrow end (remaining portion of 421) contained within the housing and in fluid communication with the assay strip, and a second, enlarged end (417) protruding from the fluid receiving end (see Figs. 11-13). Regarding claim 51, the collection strip comprises a capillary matrix adapted for rapid wicking of fluid from a fluid source to the assay strip (see col. 4,

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line 67). Regarding claim 52, the fluid source is disclosed to be an oral cavity (see abstract) as claimed; however, "the manner or method in which such a machine is to be utilized is not germane to the issue of patentability of the machine itself" *In re Casey*, 152 USPQ 235 (CCPA 1967). Regarding claim 53, the second end is of a paddle-shape (see Fig. 12). Regarding claim 54, Seymour ('492) discloses a device comprising an assay portion (416) housing a lateral flow assay strip; a neck portion (415) extending from the assay portion, the neck portion forming a channel for delivery of fluid to the assay strip (portion of 421 at and beyond 422, in a direction away from 415), the channel being defined by a first narrow port proximal to the assay portion and a second part including an opening for receiving the oral fluid, wherein the second part includes a channel width that is substantially wider than the channel width at the narrow end (see Fig. 12); and a wicking member (417 plus remaining portion of 421) in fluid communication with the lateral assay strip, the wicking member having a first portion disposed within the channel and a second portion protruding outwardly from the neck opening (see Fig. 12). Regarding claim 55, the wicking member second part is paddle shaped (see Fig. 12). While the exact scope of claim 56 is unclear, in Seymour ('492), Fig. 12, it is clear that the neck portion (415) tapers toward the end with the opening.

### **Conclusion**

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 703-308-1121. The examiner can normally be reached on 8:00 -5:30 Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



David Sorkin

September 19, 2002



W. L. WALKER  
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